REMARKS

I. STATUS OF THE CLAIMS

Prior to this amendment, claims 3-6, 8-14 and 30 were pending in this application. Upon entry of this amendment, claims 3-6 are canceled, claims 9, 11-14, and 30 are amended, and new claims 45-51 are added.

Support for the claim amendments can be found throughout the original specification as filed. Support for the amendments to claims 9 and 11 can be found, *e.g.*, at page 5, paragraphs [015] and [018], and at page 8. The amendments to claims 12-14 correct obvious grammatical mistakes in the claims. Support for the amendment to claim 30 can be found, *e.g.*, at page 1, paragraphs [001] and [002], at page 7, paragraphs [026] and [028], and at page 8. Support for new claims 45-49 can be found, *e.g.*, at page 6, paragraph [018], and at page 8; for new claim 50 at, *e.g.*, page 7, paragraph [026], and at page 8; and for new claim 51 at, *e.g.*, page 8, Example 3. No new matter is presented in this amendment.

Applicants note that the paragraph numbering relied upon by the Examiner is the numbering used in the published application (*i.e.*, 4-digit numbers), which differs from that used in the original application (*i.e.*, 3-digit numbers). Applicants, on the other hand, proceed as they have proceeded throughout the prosecution of this application. Thus, when Applicants rely on the specification by citation, they cite back to the paragraphs as originally numbered in the specification as filed.

II. OBJECTION TO THE AMENDMENTS TO THE SPECIFICATION

The Examiner maintains an objection under 35 U.S.C. § 132(a) to the amendments to paragraphs [010] and [022] of the specification made in the Amendment filed on September 20, 2005, as introducing new matter. For the reasons set forth below, Applicants traverse this rejection.

The amendments to the specification first proposed by the Applicants on September 20, 2005, merely clarified the invention as described in the original specification, and as such it is permissible according to both the M.P.E.P., *see e.g.,* section 2163.07(I), and the Federal Circuit, *see, e.g.*, Scarring Corp. v. Megan, Inc., 222

F.3d 1347, 1352-53, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000). Applicants' amendments simply rephrased the formulation of original paragraphs [010] and [022], from a formulation described as comprising:

a) one or more nonvolatile constituents,
b) urea in an amount . . ., relative to the nonvolatile constituents of the preparation,
c) a hydrophilic film-forming agent and
d) water or an alcohol-water mixture

to the formulation described as comprising :

a) nonvolatile constituents, which comprise urea in an amount . . ., relative to the nonvolatile constituents of the preparation, and a hydrophilic film-forming agent; and
b) water or an alcohol-water mixture.

As set forth by the M.P.E.P., "[b]y disclosing in a patent application a device that inherently . . . has a property . . . , a patent application necessarily discloses that [property], even though it says nothing explicit concerning it. The application may later be amended to recite the [property] . . . without introducing prohibited new matter." M.P.E.P. 2163.07(a). Applicants' amendments should not be considered new matter, because they merely recite an inherent property of urea and the claimed hydrophilic film-forming agent, which would have been known to those skilled in the art. *See, e.g.,* data sheets submitted as Attachments A and B on November 21, 2006. Thus, although the Examiner asserts that "[t]he specification as originally filed does not state that the nonvolatile constituents are urea and hydrophilic polymer," the specification need not do so.

Nevertheless, the original disclosure **does** convey that the nonvolatile constituents are urea and the hydrophilic film-forming agent in both the specification and the examples. For example, the specification states that "[t]he present invention relates to a preparation comprising urea, a hydrophilic film-forming agent and water or an alcohol/water mixture." (¶ [001]). It also states that "[t]he invention provides a preparation comprising a hydrophilic film-forming agent, urea, water and/or

alcohol/water mixture ...." (¶ [007]), and that "[t]he preparation according to the invention is an aqueous or aqueous-alcoholic solution, in which the hydrophilic film-forming agent and urea are dissolved or optionally suspended" (¶ [008]). "The preparation according to the invention is typically prepared by introducing urea and a hydrophilic film-forming agent into water or a water/alcohol mixture and subsequently mixing." (¶ [018]). Furthermore, Example 1 provides "[a] preparation according to the invention has the following composition" comprising only urea, polyvinylpyrrolidone, and demineralized water.

One skilled in the art, reading the specification and Example 1, would thus have immediately perceived that water is constituent "d) water or an alcohol-water mixture" of the original compositions, described in the original ¶¶ [010] and [022], and above. The only two constituents then left are urea and polyvinylpyrrolidone, which are b) and c), respectively. Indeed, urea is in "b) urea . . . " and polyvinylpyrrolidone is "c) a hydrophilic film-forming agent." *See also* specification, page 4, ¶ [013]. Consequently, one skilled in the art would have understood that (i) the "one or more nonvolatile constituents" were urea and polyvinylpyrrolidone simply because there is no further constituent left to take that place. Indeed, the specification states that the "urea-containing film which formed after the application to the nails was wipe-resistant and waterproof." (¶ [036]). That description of urea and a film remaining on the nails conveys that urea and the film-forming agent are nonvolatile constituents in the claimed compositions.

Applicants respectfully submit that the amendments to the specification are not new matter. Thus, Applicants respectfully request withdrawal of this objection.

III. REJECTIONS UNDER 35 U.S.C. § 112

Claims 3-6, 8-14, and 30 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement for the reasons disclosed on pages 3 - 5 of the Office Action. Although Applicants' claims no longer recite the term "nonvolatile constituents" and thus the present rejections are moot,

Applicants are compelled to comment on two erroneous statements in the present Office Action for the record.

The Examiner first asserts that "[o]rganic compounds which evaporate at **normal temperature** and pressure are considered to be volatile." Office Action at pages 3-4 (emphasis added). The Examiner then, however, goes on to rely on two documents using abnormal temperatures.

First, the Examiner provides that '[T]roetscher *et al.* in US 6,126,883 discusses that **volatile urea vapors** as well as dusts are released into the atmosphere (column 2, lines 20-25) . . . ." Office Action at pages 4-5 (emphasis added). However, the Examiner fails to point out that the "volatile urea vapors" of Troetscher *et al.* are released at temperatures **above 100°C**. Applicants' formulation is to be applied to patients' skin/nails (*see* specification, page 10), and thus would be used at room temperature, not by exposing the patients to temperatures of **100°C** and above. The context in which Troetscher's urea vapors exist is that specified in the full paragraph from which the Examiner's argument was extracted, namely:

> Another factor that must be considered is the desire to reduce the extent to which the panel manufacturing process impacts the environment. In this regard, it is a serious disadvantage of the conventional processes, that a considerable quantity of volatile binder vapors, such as formaldehyde and **urea vapors**, as well as dust and the like **are released** into the atmosphere **during the rather long time period required for reducing the temperature of the panel surfaces to approximately 100°C**.

Troetscher *et al.* in US 6,126,883, column 2, lines 20-25 (emphasis added).

Second, the Examiner argues that "paragraph [0009] of US 20070042124 recognizes urea as a volatile reagent." Office Action at page 5. However, the "volatile reagents" of US 20070042124 are referred to in the context of temperature ranges outside of the temperature range for using Applicants' formulation (patients' skin at room temperature). US 20070042124 states that "the samples were held in an air circulating dryer at a temperature of **60°C** for 16 hours, allowing the volatiles to volatilize off" (¶ [0078]) and that "[t]he emulsion thus obtained had a nonvolatile content of 45.4% upon drying at **105°C** for 3 hours" (¶ [0061]). Thus, the Examiner's statement is

erroneous and lacks support even in the citations from which it was extracted. Furthermore, it does not negate that urea is nonvolatile at "normal temperatures."

IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The Examiner rejected claims 3-6, 8-14, and 30 under 35 U.S.C. § 103(a) as obvious over Laugler *et al.* (GB 2 202 743; "Laugler GB '743") in view of Murdan ("Drug delivery to the nail following topical application," in International Journal of Pharmaceutics, Vol. 236, Issue 1-2, 2 April 2002, pages 1-26; "Murdan"), and further in view of Crandall (US 5,639,740; "Crandall '740"). Office Action at page 5. Applicants respectfully disagree and traverse this rejection.

Laugler GB '743 does not teach or suggest the presently-claimed method of hydrating brittle toenails or fingernails comprising applying the recited pharmaceutical preparation to brittle toenails or fingernails. Instead, the GB '743 disclosure relates to topical application of its preparation in the treatment of fungal infections of the nails or surrounding tissues. Laugler GB '743 does not inherently or explicitly refer to application of its preparation to brittle toenails or fingernails, and for at least this reason does not teach or suggest the claimed invention.

Laugler GB '743 also does not teach or suggest a solution having a hydrophilic film forming agent present in an amount of from 15 percent to 35 percent by weight, based on the weight of the entire solution, as presently claimed. Rather, that reference only exemplifies compositions comprising amounts outside the presently claimed range, and broadly states an "amount of from 7.5% to 30%, preferably from 10 to 20%, relative to the total weight of the composition" (page 5). None of the cited references suggest including an amount of from 15 percent to 35 percent by weight, as is presently claimed.

Laugler GB '743 also does not teach or suggest a solution having urea present in an amount of from 15 percent to 35 percent by weight, based on the weight of the entire solution, as presently claimed. Laugler GB '743 exemplifies at most 10% urea (Example IV), and states that "urea is generally present in an amount of from 1 to 20%, relative to the total weight of the composition" (page 3). The Examiner relies on Murdan for her suggestion of increasing the amount of urea in the composition. However,

Murdan was published in 2002, and thus it is not prior art to the present application, which has a foreign priority date of 2001.

The Examiner states that "[a]pplicant cannot rely upon the foreign priority papers to overcome this [§ 103] rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55." Office Action at page 8. Applicants submit herein a copy of two original documents already made of record in the parent application, namely the certified English translation of the foreign priority document "German Application 101 26 501.8, filed on May 30, 2001," and the accompanying declaration by the translator. Thus, because the priority date of the instant application precedes Murdan's publication date, Murdan does not qualify as a prior art reference.

Crandall '740, relied upon for the teaching of lactic acid, does not provide any suggestion to increase the amount of urea in Laugler GB '743 either. Rather, that reference merely states that that "invention also encompasses a method and composition for delivery of molecules into the skin." (Col. 5, ll. 21-22). One of the molecules in the list of about 20 is urea. (*Id.* at ll. 22-29). The only concentration provided is for another molecule, N-decylmethyl sulfoxide, which as said may be included "in a final concentration range of from 0.01% to 1% with a preferred range of 0.1% to 0.5%." (*Id.* at ll. 29-31). Those amounts teach away from the Examiner's proposition to increase the amount of urea in Laugler to more than the exemplified maximum of 10%.

Furthermore, the purpose of urea in Laugler GB '743 differs from that in Crandall '740. In Crandall '740, the urea is an optional ingredient that would be intended to be delivered into the skin. In contrast, Laugler GB '743 uses urea as a solubilizing agent for the miconazole nitrate and the econazole nitrate. (Page 2, 2nd full ¶). Accordingly, one of ordinary skill in the art would view the effect and the utility of increasing the amount of urea completely differently in each reference, and would not have been motivated to do so in at least Laugler GB '743.

Finally, Laugler GB '743 warns that "the weight of urea present [must] not exceed[] the weight of water present." (Page 2, 3rd full ¶). Thus, even if one of ordinary skill in the art would have been motivated to increase the amount of urea (which

Applicants do not believe would have been the case), one would have had to increase the water content of the composition as well. However, one of ordinary skill, in increasing both the water and the urea content of the composition, would not have had a reasonable expectation of success.

Since Murdan and Crandall do not remedy the deficiencies of Laugler GB '743, Applicants respectfully request that the rejection of claims 3-6, 8-14, and 30 under 35 U.S.C. § 103(a) be withdrawn.

V. CONCLUSION

For the reasons set forth above, Applicants respectfully request withdrawal of the pending objections and rejections. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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Dated: June 5, 2007

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